

Newborn Screening Quality Assurance Program

Quality Control Program
Anti-HIV-1 Antibodies in Dried Blood Spots
Instructions and Specimen Certification
Materials for Set 2, 2016
Material Expiration Date: October 2017

The enclosed shipment contains dried-blood-spot (DBS) specimens prepared on Whatman Grade 903 specimen collection paper using heat-inactivated HIV-positive serum to prepare whole blood mixtures. Do not begin using this new series of QCs until your current inventory of DBS QCs are depleted.

INSTRUCTIONS

Storage:

1. We have supplied an extra zip-closure working/storage bag with desiccant packets and humidity indicator card with your QC materials. For daily use, place a 1-month supply of blood spots from each lot in the extra working/storage bag and use only these spots until they have been depleted. (If a 1-month supply of blood spots is less than one card per lot, write the lot number in the margin of the portion of each card that you plan to cut off for daily use before you cut the card.) After you deplete this supply, transfer another month's supply to the empty bag and proceed as before.
2. Store the working bag of QC materials for daily use at 4°C; store QC materials reserves at -20°C ±10°C. Be sure that the zip-closures on all bags are sealed for storage. (Exercise caution when removing sheets of blood spots from bags stored at -20°C ±10°C. These storage bags must be allowed to acclimate to ambient temperature before they are opened.)
3. Immediately after blood spots for daily use have been removed, return the bags of reserve QC materials to -20°C ±10°C.
4. Each time you remove QC materials from the bag for daily use, check the condition of the enclosed humidity indicator card. If the card indicates elevated humidity, reactivate the card and the desiccant packets according to instructions on the working bag label.

Analysis:

1. Always punch disks for analysis from within the circles of the blood spots on the specimen cards. (For analytical information, refer to the enclosed Table: Quality Control Specimen Certification).
2. During transition phases from an old to a new series of QC lots, perform duplicate assays for the old and new QC lots in the same analytic runs. After the transition, use only the new QC lot materials.
3. Values for the control materials (serum and DBS controls) should be plotted for the purpose of monitoring trends in data and for trouble shooting for analytical problems. These plots can be helpful in detecting and monitoring lot-to-lot variation in kits, other analytical alterations, and excessive variation. We suggest you do not run dried blood spot assays without testing dried blood spot QCs, however these QCs should not be used to replace serum controls provided in the commercial kits.

This shipment contains an estimated 6-month supply from each of three quality control (QC) pools for routine use in testing your specimens. The set you have received depends on your laboratory's reported method:

- Methods 40 (Avioq HIV-1 Microelisa) and 41 (Bio-Rad HIV-1/HIV-2 plus O) users received QC pools A1507, C1507, D1507 which represent negative, low-positive, and high-positive serostatus, respectively.

- All other methods received QC pools A1507, B1507, D1507 which represent negative, low-positive, and high-positive serostatus, respectively.

Quality Control Specimen Certification

EIA SCREEN (Avioq HIV-1 Microelisa)

QC NUMBER	LEVEL	N	MEAN OD	1 SD	95% LL	95% UL
A1507	Negative	20	0.109	0.017	0.075	0.143
B1507	Low Positive	20	1.499	0.186	1.135	1.863
C1507	Low Positive	20	0.994	0.138	0.723	1.265
D1507	High Positive	20	2.203	0.191	1.829	2.577

WESTERN BLOT (Genetic Systems)

		BAND ID and SEROSTATUS								
QC NUMBER	LEVEL	160	120	66	55	51	41	31	24	18
A1507	Negative	-	-	-	-	-	+/-	-	-	-
B1507	Low Positive	++	+/-	+/-	+	+	+	+	+	-
C1507	Low Positive	++	-	+/-	+	+	+	+	+	-
D1507	High Positive	++	+	+	++	++	++	++	++	+

Our estimated usage for each participant is updated periodically on the basis of input by the laboratories.

If you believe our estimated 6-month supply is too small or too large, please let us know. Your laboratory may obtain additional QCs as needed. **Please notify us by emailing nsqapdmt@cdc.gov before November 1 for the January QC shipment.** Include your Laboratory Code Number in the subject line. Our next shipment of QC materials will be in January 2017.

Use your assigned laboratory code number when making requests and communicating data or asking questions regarding the program. If you have any comments or questions, contact Irene Williams at (770) 488-7024 or NSQAPDMT@cdc.gov.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services or the Association of Public Health Laboratories.